PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	Examiner:
Thomas F.A. Pijls	)	Monzer R. Chorbaji
	)	
Serial No.: 10/601,009	)	Art Unit: 1744
	)	
Filed: June 17, 2003	)	Conf. No.: 5778
	)	
Title: PASTEURIZING OR STERILIZING	)	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration under 37 C.F.R. § 1.132

The undersigned, Dr. Thomas Hubertus Martinus Snoeren of Bakkersveld 9, 8334 NE, Steenwijk, The Netherlands, hereby declares as follows:

I have an undergraduate degree from Wageningen University in Wageningen, from which I graduated in 1972. In 1976, I received a PhD in the fields of Food Technology and Chemistry from Wageningen University and the Netherlands Institute for Dairy Research (NIZO). The subject of my PhD thesis was, "Carrageenan, the Physiochemical Characterization and Its Interaction with Milk Proteins." From 1976 to 1980, I performed post-doctoral research on the characterization of α-s-2-casein and the isolation and characterization of plasmin.

From 1980 to 1983, I was employed by NIZO as head of the technology department concerning the concentration and drying of food products. From 1983 to 1987, I was employed by Nutricia in Zoetermeer, the Netherlands, as head of product and process development. From 1987 to 1991, I was employed by Domo Food Ingredients as director of research and quality assurance at its milk powder facility in Beilen, the

Netherlands. From 1991 to 1993, I was employed by Friesland (Frico-Domo) in Leeuwarden, the Netherlands, as research and quality assurance coordinator. From 1993 to 2006, I was employed by Numico Research as director of product and process design. From 2006 until now, I work as a technology scout. I have published several scientific papers in the fields of physical chemistry, food science, and drying of food products.

I have experience with and expert knowledge of the following topics: food product processing, especially evaporation, spray-drying, and demineralization; the physical and colloidal properties of emulsions; polymers in food products such as thickening agents, stabilizers and proteins; the interaction between biopolymers; and food product ingredients such as proteins, carbohydrates and fats.

I am familiar with the specification and claims of the above-referenced patent application as they currently stand as of the amendment and response to Office Action filed on January 22, 2007. I am also familiar with the claim amendments to be filed concurrently with this declaration in an amendment and response to the Office Action issued on April 19, 2007.

I am familiar with the Unites States Patent and Trademark Office Action of April 19, 2007, issued in conjunction with the prosecution of the above-referenced application, wherein the pending claims were rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Pisecky et al. (USPN 4,141,783) in view of Badertscher (GB 2 036 534) and Den Hollander (USPN 5,558,819), and further in view of Rubens (EP 0 438 783) or Arndt (USPN 3,843,828) or Bond et al. (USPN 5,210,958) and/or Hovmand et al. (USPN 4,062,641) or Johnston (USPN 2,401,077) or Bosund et al. (USPN 4,091,003). I am familiar with the teachings of Pisecky et al., Badertscher, Den Hollander, Rubens, Arndt, Bond et al., Hovmand et al., Johnston, and Bosund et al.

The claimed invention relates to a method for pasteurizing or sterilizing a product in liquid form comprising a heat-sensitive substance. A step of the claimed method comprises substantially atomizing the product while admixing steam in a mixing chamber heated by the steam so as to kill microorganisms and produce a pasteurized

or sterilized product. Further limitations of the claimed method include the residence time of the product in the mixing chamber being between about 0.2 msec (milliseconds) and 20 msec, and the temperature in the mixing chamber being between about 120°C and 250°C. This combination of residence time and heating temperature is critical for pasteurizing or sterilizing the product without substantially decomposing or otherwise substantially chemically altering the heat-sensitive substances in the product to an unacceptable degree.

The bactericidal effect of a heat treatment increases with increasing temperature at a much higher rate than the chemical changes induced by heat treatment (such as browning, degradation of vitamins, formation of off-flavours, etc.). The Q10 of a reaction is the factor by which the rate of reaction changes for a temperature change of 10°C. The Q10 for microorganism (spore) destruction is typically 10, while the Q10 for chemical changes is 3 (this value applies to substantially all chemical reactions). At high enough temperatures, sufficient bactericidal effect to pasteurize or sterilize a product can be reached with extremely short residence times, resulting in minimal chemical change to heat-sensitive compounds in the product.

A question has been raised as to the criticality of residence time, whether liquid product quality can be detrimentally affected at residence times above 20 msec. The calculation below deals with a comparison between residence times of 20 msec and 100 msec.

Let us consider a theoretical sterilization process designed to kill Bacillus Cereus, a sporeforming, toxin-producing pathogen. In this case, D(121°C) = 0.04 min, and Z = 9.7°C. (D is the time needed at the specified temperature to kill 90% of the pathogen; Z is the rise in temperature required to increase the killing rate 10 times). After a residence time of 20 msec at 150°C, the decimal reduction in Cereus spores would be 8.14, meaning that if an initial count of 1.4×10^8 spores/mL is present in the initial liquid product, the number of spores is reduced to 1 spore/mL after heat treatment. These conditions are more than sufficient, as a typical microorganism contamination in the liquid product would be less than 1000 spores/mL.

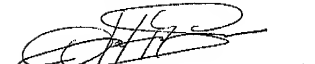
For the amount of chemical change after a residence time of 20 msec at 150°C, let us consider retention of 50% of a biologically active component (e.g., a protein, peptide or vitamin). Increasing the residence time at this temperature to 100 msec would have the same chemical and bactericidal effect as repeating the treatment five times. The bactericidal effect will increase to an irrelevantly high decimal reduction of 40.7 (meaning that an initial count of 5.0×10^{40} spores/mL would be reduced to 1 spore/mL). The effect on chemical change of a five-fold increase in residence time would be the result of 50% x 50% x 50% x 50% x 50% of the initial biological activity, that is, 3%. This is an unacceptable loss of biological activity in the liquid product. Therefore, it is critical that the residence time be minimized to the time that causes a sufficient bactericidal effect at a given temperature, so that chemical changes to heat sensitive substances in the product may be minimized to an acceptable level. At temperatures between about 120 °C and 250 °C, the critical residence time is between about 0.2 msec and 20 msec.

Den Hollander teaches a downflow heater plant wherein milk is heated with steam to a temperature of about 150°C in less than one second during its free fall, which conditions are sufficient to destroy virtually all disease germs in the milk (column 7, lines 23-29). Figures 1 and 4 show that the downflow heater device **2** has a round cylindrical central part **4** enclosing a pressure chamber **9**, through which liquid (e.g. milk) may vertically free fall (column 4, lines 17-35).

However, to the best of my knowledge, residence times of less than 20 milliseconds are not possible with the downflow heater plant as disclosed by Den Hollander. According to Newton's law, in free fall the distance fallen y can be described with this equation: $y = \frac{1}{2} g t^2$, where g is gravitational acceleration (9.8 m/s^2) and t is time in seconds. For a free fall of t = 0.2 msec to 20 msec, the distance fallen would be about y = 0.2 μm to 2.0 mm. A height of 0.2 μm to 2.0 mm is unrealistic and not useful as the height of cylindrical central part **4** or pressure chamber **9** of downflow heater device **2**, which has a width less than its height as shown in Figures 1 and 4 of Den Hollander, because the size of the device would then be so small as to render the device unfit for its original purpose of heating large amounts of liquid in a milk processing plant.

As a skilled artisan, I expect that the free fall time in the downflow heater plant as disclosed by Den Hollander would be close to one second. A free fall of about one second corresponds to a height of about 4.9 m, which is a realistic height for a downflow heater plant capable of handling large amounts of liquid. A free fall of 900 msec corresponds to a height of about 4.0 m, which is also reasonable. But a free fall of 100 msec corresponds to an unreasonably small height for a downflow heater plant of about 5.0 cm. Thus, Den Hollander's disclosure of a free fall of less than one second does not teach or suggest a residence time of 100 msec, which is one order of magnitude smaller than one second, much less a residence time of 0.2 to 20 msec, which is two to four orders of magnitude smaller than one second.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patent issuing thereon.



Dr. Thomas Snoeren

20-08-2007
Date